PATENT
512100-2046

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Hoffmann et al
U.S. Serial No.	:	10/533,926
International Application No.	:	PCT/EP2003/011529
International Filing Date	:	October 17, 2003
For	:	TRANSMUCOSAL PHARMACEUTICAL ADMINISTRATION

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on July 11, 2005

William F. Lawrence, Registration No. 28,029
Name of Applicant, Assignee or Registered Representative

Signature
July 11, 2005
Date of Signature

COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed for the Examiner's convenience is a copy of

the International Preliminary Examination Report in PCT/EP2003/011529.

Respectfully submitted,

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By _____
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From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rule 72.2)

To: Drug about water
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Eingang LTS-PAT
22. Juni 2005
iM

Date of mailing *(day/month/year)* 16 June 2005 (16.06.2005)	
Applicant's or agent's file reference 2002/112	**IMPORTANT NOTIFICATION**
International application No. PCT/EP2003/011529	International filing date *(day/month/year)* 17 October 2003 (17.10.2003)
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al	

1. **Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. **Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, CN, KR, RU

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AU, BR, EP, IL, IN, JP, MX, NZ, PH, PL, US, ZA

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Ellen Moyse
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 89 75

Form PCT/IB/338 (July 1996)

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2002/112	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/011529	International filing date (*day/month/year*) 17 October 2003 (17.10.2003)	Priority date (*day/month/year*) 08 November 2002 (08.11.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/00		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 April 2004 (30.04.2004)	18 March 2005 (18.03.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP2003/011529

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-6, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages 1-12, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL [redacted]LIMINARY EXAMINATION REPORT

International application No.
[redacted]/EP 03/11529

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations

1) Reference is made to the following documents:
The numbering of documents D1-D7 cited in the present report is based on the documents cited in the search report. This numbering will also be used in further proceedings. In particular, unless otherwise stated, the cited passages of the respective documents should be taken into account.

2) Novelty and inventive step (PCT Article 33(2) and (3))

2a) The subject matter of independent claims 1 and 2 is novel since none of the cited documents describes a transmucosal form of administration containing a mixture of a phosphatidyl choline wherein the fatty acid groups are at least 90% saturated.
In particular, D1 or D5 describes or suggests a transmucosal form of administration containing lecithin or eilecithin (see D1: claims 1 and 20; D5: column 2, line 39, claims 1-2). Standard commercial lecithin normally contains approximately the same amounts of saturated and unsaturated fatty acids. However, neither D1 or D5 nor any of the other documents suggests that the phosphatidyl cholines

employed are hydrated (conversion of the unsaturated fatty acids into saturated fatty acids), or that phosphatidyl cholines containing at least 90% saturated fatty acids are used. The claims are therefore novel over the prior art.

2b) The problem addressed by the present invention can be considered as the following: the provision of a transmucosal form of administration characterised by a low degree of solubility within the oral cavity and a quick and constant release of the agent over a longer period of time.

The solution proposed by the applicant is the use of a **phosphatidyl choline in which the fatty acids are at least 90% saturated.**

Since there is no evidence that the problem is solved by the above-mentioned phosphatidyl choline, the subject matter of the present application does not involve an inventive step.

In order for an inventive step to be acknowledged, the applicant is requested to **provide evidence** that the desired effects (lower solubility, quick but long release of agent) are based on this technical feature. The mere assertion that this is so is insufficient.

For example, the applicant could show that a phosphatidyl fraction in which the fatty acids are **only 80%** saturated will not solve the problem, whereas a phosphatidyl fraction in which the fatty acids are **90% saturated** will bring about the desired effects in the transmucosal form of administration.

The applicant's attention is drawn here to the fact that it also appears that the use of a **copolymer of the maleic acid with an alkyl vinyl ether** is an **essential feature** for solving the problem.

In the absence of evidence for the desired effects, it is not possible to acknowledge an inventive step (problem not solved) and the proposed solution is considered an obvious alternative (e.g. with respect to D1 or D5), because it appears that it is only a routine task that a person skilled in the art would carry out so as to differentiate it from the prior art.

For the regional phase:

3) Details relating to the subject matter of the invention (e.g. further details concerning the advantages of the invention or the problem of interest) but which have **no basis in the original documents, can only be mentioned in the letter of response**, but **cannot be included in the application** (PCT Article 34(2)(b)).

4) The applicant's attention is drawn to the fact that the application may not be amended in such a way that its subject matter goes beyond the content of the application as originally filed.

So as to facilitate the examination of amended application documents with respect to PCT Article 34(2)(b), the applicant is requested to indicate clearly the amendments made, whether additions, replacements or deletions, and to indicate the

passages in the originally filed application on which these amendments are based (see also PCT Rule 66.8(a)).

If desired, these details can be given in hand-written form on copies of the respective parts of the original application.